DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

9457bd

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

FEB 26 2004

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Thomas C. Stephens
President
DynaMedics Corporation
30-205 Adelaide St. N
London, Ontario
Canada N6B 3NS

Dear Mr. Stephens:

During an inspection of your establishment located in London, Ontario Canada, on October 22-23, 2003, our investigator determined that your firm manufactures alternating pressure mattresses. This product is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1) Failure to have a quality policy defined that describes the overall intentions and direction of the organization with respect to quality, as required by 21 CFR 820.20(a).

2) Failure to have a quality plan which defines the quality practices resources, and activities relevant to devices that are designed and manufactured, as required by CFR 820.20(d).

3) Failure to have a management representative appointed for ensuring that quality system requirements are effectively maintained, as required by 21 CFR 820(b)(3).

4) Failure to have quality audits or a systematic or independent examination of the quality system performed to determine whether quality system activities, and the results of such activities, comply with quality system procedures, as required by 21 CFR 820.22.

5) Failure to have quality procedures established or implemented for the following quality system activities:

a) Management Review to review the suitability and effectiveness of the quality system at defined intervals, as required by 21 CFR 820.20(c).
b) Training procedures for identifying training needs to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b).
c) Design and development planning to describe or reference the design and development activities, as required by 21 CFR 820.30(b).
d) Document controls to ensure that all quality system documents are reviewed for adequacy and approved prior to issuance, as required by 21 CFR 820.40(a).
e) Purchasing controls to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.
f) Documented instructions, standard operating procedures and methods that define and/or control the manner of production of devices, as required by 21 CFR 820.70(a)(1).
g) Written procedures for schedules for the adjustment, cleaning and other maintenance of equipment, namely sewing machines, for production of devices, as required by 21 CFR 820.70(g)(1).
h) Procedures for acceptance activities to include inspections, tests, or other verification activities for component materials or finished devices, as required by 21 CFR 820.80(b) and (d).
i) Procedure to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a).

6) Failure to have procedures for implementing corrective and preventive actions which includes analyzing processes, work operations, quality audits, quality records, and other sources of quality data, as required by 21 CFR 820.100(a)(1).

7) Failure to have a device master record for the DynaMedic Air Support Alternative Pressure Support System that describes device specifications, production process specifications, quality assurance procedures, acceptance activities, and packaging and labeling specifications, as required by 21 CFR 820.181(a),(b),(c) and (d).

8) Failure to maintain device history records for production of AynaMedic Air Support Alternative Pressure Support System, as required by 21 CFR 820.184.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice, which may include detaining your devices without physical examination upon entry into the Untied States until corrections are completed. 21 U.S.C. § 381(a). In addition, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Include all documentation of the corrective action you have taken.

Your response should be sent to Rebecca Keenan, Compliance Officer, Food and Drug Administration, 2094 Gaither Road, Rockville, MD, USA 20850. Ms. Keenan may also be reached by telephone at 301-594-4618 and by fax at 301-594-4638.

Sincerely yours,

Larry D. Stephens for

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health